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SMDA/510(k) Summary:

510(k) Summary 30 January 2002

This 510(k) summary for safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

Paul Schrader
Quality and Regulatory Manager
Philips Medical Systems
3000 Minuteman Road, Andover, MA 01810-1085
Tel: 978 659 2404 Fax: 978 659 7360

2. Unique Identifier for Submittal: EASI 12 Lead Algorithm / Coefficients

Classification	ProCode	Description
870.2350	DRW	Adapter, Lead switching, electrocardiograph

3. The new device is a modification to previously reviewed submittals containing the EASI algorithm.

4. The modification is a software-based change that slightly improves existing correlation coefficients. The modification also allows reconstruction to simulate a Mason Likar lead placement.

5. The new device has the same technological characteristics as the legally marketed predicate device.

6. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved 2 physician over-reads comparing the modified coefficients to traditional 12 Lead ECG and Mason Likar 12 Lead ECG on the same patients. A comparison of the correlation coefficients from earlier studies on the same patients was done. The modified coefficients did not show a decreased correlation in any of the leads. Several of the leads showed improvements with the improvement in the correlation coefficient varying from 0 to 0.10 in one case. It was therefore concluded that the modification does not increase patient risk relative to what is on the market today. It does improve effectiveness in some of the leads based on the data gathered.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2002

Phillips Medical System
c/o Mr. Paul M. Schrader
Q&R Manger Cardiology Division
3000 Minuteman Road
Andover, MA 01810-1085

Re: K020456
Device Name: EASI 12 LEAD ™ 12 Lead Coefficients
Regulation Number: 21 CFR 870.2350
Regulation Name: Adapter, Lead Switching, ECG
Regulatory Class: Class II (two)
Product Code: 74DRW
Dated: February 7, 2002
Received: February 11, 2002

Dear Mr. Schrader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020456

Indications for Use Statement

510(k) Number: K020456
Device Name: EASI 12 LEAD™ 12 Lead Coefficients

Indications for Use:

Assessment of real time ST segment analysis in adult patients. Assessment is indicated for the hospital environment.

Note to Users on Patient Population:

Based on the FDA review of K992595 the following labeling must be disclosed within user documentation for EASI 12 LEAD ST Analysis:
Assessment of EASI 12 LEAD derived 12-lead ST measurements is recommended for adult patients that meet the following parameters:

- Ages 33 to 82 years
- Heights: 147 to 185 cm (58 to 73 in)
- Weights: 53 to 118 kg (117 to 261 lbs.)
- Height to Weight Ratios: 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb.)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular and Respiratory Devices
510(k) Number K020456

Prescription Use X OR over-the-counter Use
(Per 21 CFR 801.109)